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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,088	01/18/2007	Zoran Gojkovic	GOJKOVIC3	7165

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,088	GOJKOVIC, ZORAN	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,26-43,46-50 and 55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22,26-43,46-50 and 55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-9, 16, 19, 20, 22 and 55, drawn to a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes a multisubstrate deoxyribonucleoside kinase, a vector comprising the polynucleotide, and a host cell comprising the vector that may be cultured to produced the encoded polypeptide- i.e, not a gene therapy host cell.

Group 2, claim(s) 10-15 and 30, drawn to a polypeptide derived from an *Aedes aegypti* polypeptide that is a multisubstrate deoxyribonucleoside kinase, or a composition comprising the polypeptide and a cancer drug.

Group 3, claim(s) 16-21, 31 and 32, drawn to a host cell comprising a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes a multisubstrate deoxyribonucleoside kinase, the host cell being suitable for gene therapy- i.e., a virus, a stem cell or an embryonic cell, or a composition comprising the host cell and a cancer drug.

Group 4, claim(s) 26-29, drawn to a gene therapy composition for treating cancer, comprising a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes a multisubstrate deoxyribonucleoside kinase and a cancer drug.

Group 5, claim(s) 33-35, drawn to a method of sensitizing a cell to a prodrug, comprising transfecting the cell with a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes a multisubstrate deoxyribonucleoside kinase and a nucleoside analogue prodrug.

Group 6, claim(s) 36-43, drawn to a gene therapy method of inhibiting a pathogenic agent by administering a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes a multisubstrate deoxyribonucleoside kinase.

Group 7, claim(s) 46-47, drawn to a method of phosphorylating a nucleoside by contacting it with a polypeptide derived from an *Aedes aegypti* polypeptide that is a multisubstrate deoxyribonucleoside kinase.

Group 8, claim(s) 48-50, drawn to a method of performing nuclear imaging to measure the transgenic expression in a cell or subject of a polypeptide derived from an *Aedes aegypti* polypeptide that is a multisubstrate deoxyribonucleoside kinase.

The inventions listed as Groups 1-36 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features. The technical feature that links the 8 groups of inventions is a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes a multisubstrate deoxyribonucleoside kinase, or the encoded protein, or a polynucleotide having at least 70% sequence identity to SEQ ID NO:1, or a protein having at least 80% sequence identity to this protein.

The inventions of Groups 1-8 do not share the common special technical feature of a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes a multisubstrate deoxyribonucleoside kinase, or the encoded protein, or a polynucleotide having at least 70% sequence identity to SEQ ID NO:1, or a protein having at least 80% sequence identity to this protein, because Knecht et al. "Mosquito has a single mutlisubstrate deoxyribonucleoside kinase characterized by unique substrate specificity," Nucleic Acids Res 31(6):1665-1672, March 2003 disclose a multisubstrate deoxyribonucleoside kinase encoded by a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes this protein, as well as a protein having 82% sequence identity to SEQ ID NO:2. See p. 6, second alignment, of the enclosed "Blast" sequence comparisons, searches performed in the NCBI database on March 24, 2008. See also Knecht et al., p. 1670, Fig. 3.

Thus, the technical feature of a polynucleotide derived from an *Aedes aegypti* polynucleotide that encodes a multisubstrate deoxyribonucleoside kinase, or the encoded protein, or a polynucleotide having at least 70% sequence identity to SEQ ID NO:1, or a protein having at least 80% sequence identity to SEQ ID NO:2, does not define the invention over the prior art. Because the common technical feature is not novel (special) with respect to the cited reference, it is clear that the claims of Groups 1-8 lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)). In the instant case, the claims are drawn to multiple products and multiple processes, only a particular combination of which including Group 1 may be considered for unity of invention, i.e., Group 1 and Group 5, (the first named product and the first named process of using the product). Other groups are drawn to additional products and processes, and other combinations do not comply with the aforementioned Rules. But, because a corresponding special technical feature is not present, Groups 1 and 5 cannot be considered to have unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows.

a) If Applicant elects Group 3, in claim 17, Applicants must elect one of the viral vectors recited in the claim.

b) If Applicant elects Group 3, in claim 21, Applicants must elect either stem cells or human precursor cells (embryonic cells).

c) If Applicant elects Group 4, in claims 27-28, Applicants must elect one of the drugs listed- a cytidine analogue or Gemcitabine or AraC.

d) If Applicant elects Group 5, in claims 34-35, Applicants must elect one of the drugs listed- a cytidine analogue or Gemcitabine or AraC.

e) If Applicant elects Group 6, in claims 38-40, Applicants must elect one of the pathogenic agents listed- a virus, or a bacterium, or a parasite, or a tumor cell, or an autoreactive immune cell.

f) If Applicant elects Group 6, in claims 42-43, Applicants must elect one of the drugs listed- a cytidine analogue or Gemcitabine or AraC.

Applicant is required, in reply to this action, to elect a single species in a) – f) above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 17, 20, 26, 33, 36 and 41.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Claim 17 recites different vectors, each of which has a different structure and different biological and chemical properties and requires a distinct and separate search. Claim 21 recites different cell types, each of which has different biological and chemical properties and requires a distinct and separate search. Claims 27, 28, 34, 35, 42 and 43 recite different drugs, each of which has a different structure and different biological and chemical properties and requires a distinct and separate search. Claims 38-40 recite various types of microorganisms and animal cells, each of which has a different structure and different biological and chemical properties and requires a distinct and separate search. Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In

re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

/Elizabeth Slobodyansky, PhD/
Primary Examiner, Art Unit 1652

rk/2008-03-25